

DEFENDANT AMERIDOSE, LLC'S
ANSWER AND AFFIRMATIVE
DEFENSES TO PLAINTIFFS'
AMENDED COMPLAINT

KIMBERLEY YVETTE SMITH-MARTIN,)
M.D.,)
)
and)
)
JOHN DOE(S) CORPORATIONS (1-4),)
)
and)
)
JOHN DOE(S), M.S. (1-3))
)
)
Defendants.)
)

Defendant Ameridose, LLC, by and through its undersigned counsel, hereby answers
Plaintiffs' Amended Complaint as follows:

PARTIES

1. No response is required for Paragraph 1.
2. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2.
3. The allegations in Paragraph 3 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 3 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.
4. The allegations in Paragraph 4 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 4 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

5. Defendant denies that it is a corporation, but states that it is a Massachusetts Limited Liability Company with a principal place of business located at 205 Flanders Road, Westborough, MA 01581.

6. Defendant admits that it is in the business of manufacturing, compounding, marketing, and selling certain medications. Defendant denies that it manufactured, compounded, marketed, and/or sold methylprednisolone acetate (MPA).

7. The allegations in Paragraph 7 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 7 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

8. The allegations in Paragraph 8 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 8 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

9. Defendant admits that it has common ownership with Defendants NECC and Alaunus. Defendant denies the remaining allegations against it in Paragraph 9.

10. No response is required for Paragraph 10.

11. The allegations in Paragraph 11 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 11 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

12. The allegations in Paragraph 12 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph

12 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

13. The allegations in Paragraph 13 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 13 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

14. The allegations in Paragraph 14 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 14 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

15. The allegations in Paragraph 15 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 15 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

16. The allegations in Paragraph 16 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 16 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

17. The allegations in Paragraph 17 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 17 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

18. The allegations in Paragraph 18 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 18 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

19. The allegations in Paragraph 19 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 19 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

20. The allegations in Paragraph 20 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 20 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

FACTS

21. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 21.

22. Defendant denies that it manufactured and/or compounded MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 22 as to the other Defendants.

23. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 23.

24. Defendant denies that it manufactured and/or compounded MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24 as to the other Defendants.

25. Defendant denies that it manufactured and/or compounded MPA. Defendant denies the remaining allegations against it in Paragraph 25 and lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations as to the other Defendants.

26. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26.

27. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27.

28. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28.

29. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 29.

30. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 30.

31. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 31.

**COUNT I – VIOLATIONS OF THE PRODUCT LIABILITY ACT,
N.J. STAT. § 2A:58C-1 TO 7**

JENNA S. LETIZIA and PAUL LETIZIA

V.

**NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW ENGLAND
COMPOUNDING CENTER, AMERIDOSE, LLC, ALAUNUS PHARMACEUTICAL,
LLC, PREMIERE ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF
SOUTHERN NEW JERSEY, LLC, also trading as PREMIERE ORTHOPAEDIC
ASSOCIATES, PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC
AND JOHN DOE(S) CORPORATIONS (1-4)**

32. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

33. Defendant denies that it manufactured, compounded, and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33 as to the other Defendants.

34. Defendant denies that it manufactured, compounded, and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34 as to the other Defendants.

35. Defendant denies that it manufactured, compounded, distributed and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 35 as to the other Defendants.

36. Defendant denies that it manufactured, compounded, and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36 as to the other Defendants and Plaintiff's injuries.

37. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 37.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Amended Complaint.
Defendant demands a trial by jury.

COUNT II – NEGLIGENCE

JENNA S. LETIZIA and PAUL LETIZIA

V.

**NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW ENGLAND
COMPOUNDING CENTER, AMERIDOSE, LLC, ALAUNUS PHARMACEUTICAL,
LLC AND JOHN DOE(S) CORPORATIONS (1-4)**

38. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

39. Defendant denies that it manufactured, compounded and/or sold MPA. Defendant is not required to respond to the allegations in Paragraph 39 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

40. Defendant denies that it manufactured, compounded, sold, tested and/or distributed MPA. Defendant is not required to respond to the allegations in Paragraph 40 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

41. Defendant denies that it designed, manufactured, compounded, tested, warned, marketed and/or sold MPA. Defendant is not required to respond to the allegations in Paragraph 41 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- a. Defendant denies that it shipped MPA. Defendant is not required to respond to the allegations in Paragraph 41(a) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- b. Defendant is not required to respond to the allegations in Paragraph 41(b) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information

sufficient to form a belief about the truth of the allegations as to the other Defendants.

- c. Defendant is not required to respond to the allegations in Paragraph 41(c) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- d. Defendant is not required to respond to the allegations in Paragraph 41(d) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- e. Defendant is not required to respond to the allegations in Paragraph 41(e) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- f. Defendant is not required to respond to the allegations in Paragraph 41(f) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- g. Defendant denies that it designed, compounded and/or manufactured MPA.

Defendant is not required to respond to the allegations in Paragraph 41(g) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- h. Defendant denies that it tested MPA. Defendant is not required to respond to the allegations in Paragraph 41(h) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- i. Defendant denies that it compounded MPA. Defendant is not required to respond to the allegations in Paragraph 41(i) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- j. Defendant denies that it manufactured and compounded MPA. Defendant is not required to respond to the allegations in Paragraph 41(j) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- k. Defendant is not required to respond to the allegations in Paragraph 41(k) that set forth legal conclusions. However, to the extent that such allegations may be

construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

42. Defendant is not required to respond to the allegations in Paragraph 42 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

43. Defendant is not required to respond to the allegations in Paragraph 43 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Amended Complaint.

Defendant demands a trial by jury.

COUNT III – NEGLIGENCE

**JENNA S. LETIZIA and PAUL LETIZIA
V.**

**PREMIERE ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF
SOUTHERN NEW JERSEY, LLC, also trading as PREMIERE ORTHOPAEDIC
ASSOCIATES, PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC,
KIMBERLEY YVETTE SMITH, M.D. a/k/a KIMBERLEY YVETTE SMITH-MARTIN,
M.D., JOHN DOE(S) CORPORATIONS (1-4), AND JOHN DOE, M.D. (1-3)**

44. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

45. The allegations in Paragraph 45 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph

45 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

46. The allegations in Paragraph 46 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 46 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

a. The allegations in Paragraph 46(a) are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 46(a) for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

b. Defendant denies that it manufactured and/or compounded MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 46(b) as to the other Defendants.

47. The allegations in Paragraph 47 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 47 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Amended Complaint.
Defendant demands a trial by jury.

COUNT IV – BREACH OF EXPRESS WARRANTY

JENNA S. LETIZIA and PAUL LETIZIA

V.

**NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW ENGLAND
COMPOUNDING CENTER, AMERIDOSE, LLC, ALAUNUS PHARMACEUTICAL,
LLC, AND JOHN DOE(S) CORPORATIONS (1-4)**

48. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

49. Defendant denies that it made any warranties or representations regarding MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 49 as to the other Defendants.

50. Defendant denies that it made any warranties or representations regarding MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50 as to the other Defendants.

51. Defendant denies that it manufactured and/or sold MPA. Defendant is not required to respond to the allegations in Paragraph 51 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Amended Complaint. Defendant demands a trial by jury.

COUNT V – LOSS OF CONSORTIUM

JENNA S. LETIZIA and PAUL LETIZIA

V.

NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW ENGLAND COMPOUNDING CENTER, AMERIDOSE, LLC, ALAUNUS PHARMACEUTICAL, LLC, PREMIERE ORTHOPAEDIC AND SPORTS MEDICINE ASSOCIATES OF SOUTHERN NEW JERSEY, LLC, also trading as PREMIERE ORTHOPAEDIC ASSOCIATES, PREMIER ORTHOPAEDIC ASSOCIATES SURGICAL CENTER, LLC, KIMBERLY YVETTE SMITH, M.D. a/k/a KIMBERLEY YVETTE SMITH-MARTIN, M.D., JOHN DOE(S) CORPORATIONS (1-4), AND JOHN DOE(S), M.D. (1-3)

52. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

53. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 53.

54. Defendant is not required to respond to the allegations in Paragraph 54 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Amended Complaint. Defendant demands a trial by jury.

DEFENSES AND AFFIRMATIVE DEFENSES

During the course of litigation, a number of defenses and/or affirmative defenses may become available to Defendant. To the extent any of the following are available and may apply, notice is hereby given of the following:

1. The Amended Complaint fails to state a claim or cause of action cognizable in law or equity against Defendant Ameridose.

2. The Amended Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy as to Defendant Ameridose.

3. Plaintiffs lack standing to sue Defendant Ameridose.

4. Defendant did not make the product in question and has no liability here since it is a separate entity not responsible for the acts of the other Defendants.

5. The allegations of the Amended Complaint do not adequately set forth the elements required to overcome the presumption of corporate separateness under applicable state law.

6. The Amended Complaint fails to sufficiently identify a preparation compounded or manufactured by this Defendant.

7. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of Defendant, including Plaintiffs' comparative fault, pre-existing medical condition, and/or idiosyncratic reaction.

8. The Defendant further states that if the Plaintiffs underwent the medical procedure, they did so after having been fully, fairly, and reasonably informed and made aware of risks and uncertainties involved, and that after having been so informed consistent with the informed consent and or incurred risk doctrines of New Jersey, they exercised their informed consent to the performance of the procedure.

9. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

10. Defendant relies upon all applicable defenses afforded it under the New Jersey Products Liability Act of 1987, N.J.S.A. 2A:58C-1, *et seq.*

11. To the extent that Plaintiffs' claims are based on violations of the Federal Food Drug & Cosmetic Act, such claims must fail since there is no private right of action regarding these alleged violations.

12. Plaintiffs' alleged injuries and/or damages, if any, were caused or contributed to by entities other than this Defendant and those named as Defendants in this action. Fault and a percentage of liability must be apportioned to all who caused or contributed to the Plaintiffs' alleged injury under applicable state law.

13. Defendant incorporates and adopts by reference any and all applicable affirmative defenses, raised or to be raised by any other party, and expressly reserves the right to amend and supplement its Answer or to assert additional affirmative defenses at or before trial as additional information is obtained through investigation and discovery.

WHEREFORE, Defendant demands Judgment of this Court:

- a. dismissing the Complaint against it, with prejudice;
- b. awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. granting such other and further relief, both legal and equitable, that the Court deems just and proper.

Dated: January 3, 2013

DENIAL OF ALL CROSS CLAIMS

Defendant denies any and all cross claims asserted or to be asserted against it and further denies that it is in any way liable to any party for contribution, indemnity or any other theory of law or equity, regardless of whether such party is found liable in this matter. All of the separate affirmative defenses set forth above are hereby incorporated by reference as to any party now or later asserting cross claims against Defendant.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I certify under penalty of perjury that the matter in controversy is not subject to any other known action pending in any court or of any pending arbitration of administrative proceeding.

Respectfully submitted,

s/ Walter F. Timpone

Walter F. Timpone

Walter R. Krzastek

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Attorneys for Defendant Ameridose, LLC

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on January 3, 2013 using the ECF system that sent notification of this filing to all ECF-registered counsel of record via e-mail generated by the Court's ECF system.

s/ Walter F. Timpone

Attorney for Defendant Ameridose, LLC